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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/323,738 06/01/99 OSBORNE

W P-UW-3570

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HM22/0328

EXAMINER

VANDER VEGT, F

ART UNIT

PAPER NUMBER

1644

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DATE MAILED:

03/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.  
09/323,738

Applicant(s)  
Osborne et al

Examiner  
F. Pierre VanderVegt

Group Art Unit  
1644



☒ Responsive to communication(s) filed on Dec 11, 2000

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-40 ~~is/are~~ pending in the application.

Of the above, claim(s) 1-16 and 40 ~~is/are~~ withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 17-39 ~~is/are~~ rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

### DETAILED ACTION

This application is a continuation-in-part of application serial number 09/185,852, which claims priority to provisional application 60/087,660.

Claims 1-40 are currently pending in this application.

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#### *Election/Restriction*

1. Applicant's election with traverse of Group II, claims 17-39, in Paper No. 9, filed December 11, 2000, is acknowledged. The traversal is on the ground(s) that the search of both groups would not constitute an undue burden upon the Examiner. This is not found persuasive because of the reasons previously stated.

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The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-16 and 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

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Claims 17-39 are the subject of examination in this Office Action.

#### *Claim Rejections - 35 USC § 112*

3. Claims 17-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for supplementing insulin supply in a patient in a treatment of diabetes, does not reasonably provide enablement for preventing diabetes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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The claims are drawn to the treatment or prevention of diabetes in an individual by the administration of cells modified to express proinsulin in a glucose-dependent manner. Said proinsulin production would supplement the insulin production of the subject. This supplementation would not, however, be able to prevent diabetes in the subject. In order to prevent a condition, a treatment must be able to address to root cause of said condition. It has

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been well established that much of the symptomology of the various conditions which fall under the broad classification of "diabetes" is due to the inability of the individual to produce sufficient amounts of insulin, e.g., due to autoimmune destruction of beta cells, or an inability of normally insulin-responsive cells/tissues to properly/adequately respond to insulin signal, e.g., insulin resistance. It has also been long established that a mode of treatment of diabetes is to administer insulin to a diabetic subject to replace or augment said patient's endogenous insulin supply. It is recognized in the art that this method of treatment is not preventative or curative, as the subject will still have diabetes, but alleviates symptoms of the subject's condition associated with the paucity of insulin production or response. It is respectfully submitted that the instantly claimed method merely constitutes a method of insulin supplementation. While the claimed method may be more eloquent than current methods of treatment comprising manual determination of blood glucose levels and responsive insulin injections by supplying the subject with an in vivo source of insulin production which reduces the requirement for periodic injections of insulin, the introduced cells do not address the root cause of the insulin lack/unresponsiveness. One skilled in the art at the time the invention was made would not be able to predict that the instant method would be able to prevent the onset or progression of diabetes in an individual. It would take an undue amount of experimentation on the part of the artisan to further modify the cells of the claimed method in a way that could prevent diabetes onset. The instant specification does not provide any guidance regarding such modification.

In view of the state of the prior art, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

### *Conclusion*

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

5. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

- Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2001 365-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

- 15 F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
Technology Center 1600  
February 26, 2001



**F. PIERRE VANDERVEGT**  
**PATENT EXAMINER**